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PATENT

Docket No.: 29853/37702

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Zh

Zhang, et al.

Serial No.:

10/033,571

Filed:

December 27, 2001

For:

Method for Producing Purified

Adenoviral Vectors

Art Unit:

Not Assigned

Examiner:

Not Assigned

I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on this

date:

May 28, 2002

Jeffrey Sharp

Registration No. 31,879 Attorney for Applicant(s)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, D.C. 20231

Sir:

The patents and publications listed on the enclosed PTO Form-1449 are submitted pursuant to 37 CFR §§ 1.56, 1.97, and 1.98. Copies of the patents and publications believed not to be of record in the parent case (see below) are enclosed as necessary, and are marked with an asterisk (*).

TIME OF FILING

This information disclosure statement is being filed:

- 1. with the application or within three months of the filing date of the application or date of entry into the national stage of an international application or, to the best of the undersigned's knowledge, before the mailing date of a first Office Action on the merits, whichever event occurs last. In accordance with 37 CFR §1.97(b), no certification or fee is required.
- □ 2. after the time period specified in paragraph 1 above, but, to the best of the undersigned's knowledge, before the mailing date of a final action under 37 CFR §1.113 or notice of allowance under 37 CFR §1.311. Therefore, in accordance with 37 CFR §1.97(c), submitted herewith is:

(check either A or B below)

Α.		a certification as specified in 37 CFR §1.97(e).
	the fee	set forth in 37 CFR §1.17(p) for submission of an information
	disclosi	re statement under 37 CFR §1.97(c).

- after the mailing date of either a final action under 37 CFR §1.113 or a notice of allowance under 37 CFR §1.311, whichever occurs first, but before payment of the issue fee. Therefore, Applicant submits herewith:
 - A. a certification as specified in 37 CFR §1.97(e);
 - B. the petition fee set forth in 37 CFR §1.17(i); and
 - C. the accompanying petition under 37 CFR §1.97(d).

PRIOR AND RELATED APPLICATIONS

In accordance with 37 CFR §1.98(d), most copies of the patents and publications listed on the enclosed PTO Form-1449 are not provided because the patents and publications were previously cited by, or submitted to, the Patent Office in a prior application that Applicant(s) rely upon for an earlier filing date under 35 U.S.C. §120. Documents listed on the attached Form PTO-1449 were cited by, or submitted to, the examiner of the following patent application(s):

Applicants: Serial No. Zhang, et al.

Filing Date:

09/556,570 April 24, 2000

Title:

An Improved Method for the Production and

Purification of Adenoviral Vectors

Status:

Issued as Patent No. 6,194,191 B1

METHOD OF PAYMENT

No fee is required.
Attached is a check in the amount of \$

The Commissioner is authorized to charge any fee deficiency required by this paper, or credit any overpayment, to Deposit Account No. 13-2855. A copy of this paper is enclosed.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN 6300 Sears Tower 233 South Wacker Drive Chicago, Illinois 60606-6357 (312) 474-6300

By:

Jeffrey S. Sharp Reg. No: 31,879

May 28, 2002

			U.S. PAT	TENT DOCUMENTS		-	
*Examiner Initials		Document Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
		4,352,883	10/05/82	Lim	435	178	
		4,725,547	02/16/88	Sakamoto, et al.	435	239	
		5,607,851	03/04/97	Pellegrini, et al.	435	236	
	*	5,744,304	04/28/98	Munford	436	6	
	*	5,837,520	11/17/98	Shabram, et al.	435	239	

		F	OREIGN PAT	FENT DOCUM	MENTS		
*Examiner		Document Number	Publication Date	Country	Class	Subclass	Translation
	*	4-9338	01/14/92	JAPAN			
	*	0 475 623 A1	03/18/92	EPO			
	*	WO 93/25224	12/23/93	PCT			
	*	WO 94/06910	03/31/94	PCT			
		WO 94/17178	08/04/94	PCT			
		WO 95/25789	08/28/95	PCT			
		WO 96/27677	09/12/96	PCT			
	*	WO 97/04803	02/13/97	PCT			
		WO 97/08298	03/06/97	PCT			
	-	WO 98/00524	01/08/98	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
Aboud, et al., "Rapid purification of extracellular and intracellular moloney murine leukemia virus," <i>Arch. Virol.</i> , 71:185-195, 1982.
Berg, et al., "High-live expression of secreted proteins from cells adapted to serum-free suspension culture," <i>BioTechniques</i> , 14(6):972-978, 1993.
Bett, "An efficient and flexible system for construction of adenovirus vectors with insertions or deletions in early regions 1 and 3," <i>Proc. Natl. Acad. Sci. USA</i> , 91(19):8802-8806, 1994.

EXAMINER.	DATE

Form PTO-1449 (Modified) JUN 0 3 2002 INFORMATION DISCLOSURE STATEMENT

U.S. Department of Commerce Patent and Trademark Office

Atty: Docket No. Serial No 29853/37702 10/033,571 Applicant Zhang, et al. Filing Date Group

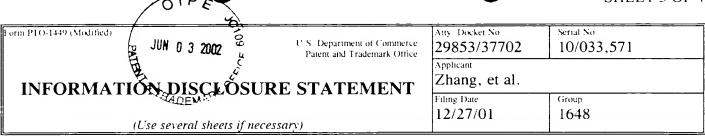
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12/27/01

(Use several sheets if necessary)

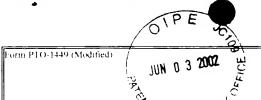
	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
*	Cartwright, Terrance, "Animal cells as bioreactors," Cambridge University Press, pp. 58-63, 1994
*	Complaint Aventis Pharmaceuticals Products, Inc. and Aventis Pharma, S.A., Plaintiffs, v. Introgen Therapeutics, Inc., Defendant. Civil Action No. O1-451 from the U.S. District Court for the District of Delaware, June 29, 2001, dismissed with prejudice July 2, 2001.
	Crooks, et al., "Purification and analysis of infections virions and native non-structural antigens from cells infected with tick-borne encephalitis virus," <i>J. Chrom.</i> , 502:59-68, 1990.
	Garnier, et al., "Scale-up of the adenovirus expression system for the production of recombinant protein in human 293S cells," <i>Cytotechnol.</i> , 15:145-155, 1994.
	Gilbert, "Adaptation of cells to serum-free culture for production of adenovirus vectors and recombinant proteins," <i>Williamsburg BioProcessing Conference</i> , Nov. 18-21, 1996.
	Graham and Prevec, "Manipulation of adenovirus vectors," Int. Methods in Molecular Biology: Gene Transfer and Expression Protocols 7, (Murray, Ed.) Humana Press, Clifton, NJ, pp. 109-128, 1991.
	Graham, et al., "Characteristics of a human cell line transformed by DNA from human adenovirus type 5," J. Gen. Virol., 36:59-72, 1977.
	Graham, "Growth of 293 Cells in Suspension Culture," J. Gen. Virol., 68:937-940, 1987.
	Griffiths, "Overview of cell culture systems and their scale-up," <i>In: Animal Cell Biotechnology</i> , 3:179-220, 1986.
	Hay, et al., "Replication of adenovirus mini-chromosomes," J. Mol. Biol., 175:493-510, 1984.
	Hearing and Shenk, "Functional analysis of the nucleotide sequence surrounding the cap site for adenovirus type 5 region EIA messenger RNAs," <i>J. Mol. Biol.</i> , 167:809-822, 1983.
	Hearing, et al., "Identification of a repeated sequence element required for efficient encapsidation of the adenovirus type 5 chromosome," J. Virol., 61:2555-2558, 1987
	Huyghe, et al., "Purification of a type 5 recombinant adenovirus encoding human p53 by column chromatography," <i>Hum. Gene Ther.</i> , 6:1403-1416, 1996.
	International Search Report dated July 16, 1998 (PCT/US97/21504) (INGN:058P).
	Jones and Shenk, "Isolation of deletion and substitution mutants of adenovirus type 5, <i>Cell</i> , 13:181-188, 1978.
	Larsson and Litwin, "The growth of polio virus in human diploid fibroblasts grown with cellulose microcarriers in suspension cultures," <i>Dev. Bio. Standard</i> , 66:385-390, 1987.

EXAMINER:	DATE:



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	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
	Lentfer, D. and Conde, C., "A Rapid and Inexpensive Procedure for the Purification of Adenovirions" 1978.
	Levrero, et al., "Defective and nondefective adenovirus vectors for expressing foreign genes <i>in vitro</i> and <i>in vivo</i> ," <i>Gene</i> , 101:195-202, 1991.
	Mann, et al., "Construction of a retrovirus packaging mutant and its use to produce helper-free defective retrovirus," <i>Cell</i> , 33:153-159, 1983.
	McGrath, et al., "Retrovirus purification: method that conserves envelope glycoprotien and maximizes infectivity" J. Virol., 25:923-927, 1978.
	Mizrahi, "Production of human interferons-an overview," <i>Proc. Biochem.</i> , (August):9-12, 1983.
	Montagnon, B.J., "Polio and Rabies Vaccines Produced in Continuous Cell Lines: A Reality for Vero Cell Line" 1989.
	Morris, et al., "Serum-free production of adenoviral vectors for gene therapy," Williamsburg BioProcessing Conference, Nov. 18-21, 1996.
*	Nadeau, et al., "Improvement of Recombinant Protein Production with the Human Adenovirus/293S Expression System Using Fed-Batch Strategies," <i>Biotechnology and Bioengineering</i> 51:613-23, 1996.
	Nicolas and Rubenstein, "Vectors: a survey of molecular cloning vectors and their uses," <i>In: Vectors: A survey of molecular cloning vectors and their uses</i> , (Rodriguez and Behhardt, eds.), Stoneham: Butterworth, pp. 493-513, 1988.
	Nilsson and Mosbach, "Immobilized animal cells," Dev. Biol. Standard, 66:183-193.
	O'Neil and Balkovic, "Virus harvesting and affinity-based liquid chromatography," <i>Bio. Technol.</i> , 11:173-178, 1993.
*	Payment, et al., in <i>Biotechnology Current Progress</i> , Eds. Paul Cheremisinoff and Louise Ferrante, Technomic Publishing Co., Lancaster/Basel, Vol. 1, pp. 61-82, 1991.
	Perrin, et al. "An experimental rabies vaccine produced with a new BHK-21 suspension cell culture process; use of serum-free medium and perfusion-reactor system," <i>Vaccine</i> , 13(13):1244-1250, 1995.
	Petricciani, "Should continuous cell lines be used as substrates for biological products?," <i>Dev. Biol. Standard</i> , 66:3-13, 1985.
	Phillips, et al., "Experience in the cultivation of mammalian cells on the 8000 1 scale," <i>In: Large Scale Mammalian Cell Culture</i> (Feder and Tolbert, eds.), Academic Press, Orlando, FL, U.S.A., 1985.
	Provisional U.S. Patent Application Serial No. 60/026,667, Entitled: "METHOD FOR THE PRODUCTION OF RECOMBINANT ADENOVIRUSES," RPR File No. ST96021-U.S., Translated from the French by the Medical Documentation Service® Institute for Scientific Information® Philadelphia, Pennsylvania.

EXAMINER	DATE	
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U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCEOSURE STATEMENT

(Use several sheets if necessary)

	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)
	Roux, et al., "A versatile and potentially general approach to the targeting of specific cell types by retroviruses: application to the infection of human cells by means of major histocompatibility complex class I and class II antigens by mouse ecotropic murine leukemia virus-derived viruses," <i>Proc. Nat 'I Acad. Sci. USA</i> , 86:9079-9083, 1989.
	Smith and Lee, "Large-scale isolation and partial purification of type C RNA viruses on hydroxyapatite," <i>Analytical Biochem.</i> , 86:252-263, 1978.
	Temin, "Retrovirus vectors for gene transfer: efficient integration into and expression of exogenous DNA in vertebrate cell genomes," <i>In: Gene Transfer</i> , (Kucherlapati, ed.) Plenum Press, New York, pp. 149-188, 1986.
	Tibbetts, "Viral DNA sequences from incomplete particles of human adenovirus type 7," <i>Cell</i> , 12:243-249, 1977.
*	Trepanier, et al., "Concentration of Human Respiratory Syncytial Virus Using Ammonium Sulfate, Polyethylene Glycol or Hollow Fiber Ultrafiltration," <i>Journal of Virological Methods</i> 3:201-211, 1981.
	van Wezel, "Growth of cell-strains and primary cells on micro-carriers in homogeneous culture," <i>Nature</i> , 216:64-65, 1967.
	Wang, et al., "High cell density perfusion culture of hybridoma cells for production of monoclonal antibodies in the celligen packed bed reactor," <i>In:Animal Cell Technology: Basic & Applied Aspects</i> , (Kaminogawa, et al., eds), Kluwer Academic Publishers, Netherlands, 5:463-469, 1993.
	Wang, et al., "Modified CelliGen-packed bed bioreactors for hybridoma cell cultures," <i>Cytotechnol.</i> , 9:41-49, 1992.
*	Wills, et al., "Adenovirus Vectors of Gene Therapy of Cancer," <i>Journal of Cellular Biochemistry</i> ," Supp. 17E, S216:206, 1993.

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